DEPARTMENT OF HEALTH & HUMAN SERVICES 20 Public Health Service

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Food and Drug Administration
Rockville MD 20857

MAY 31 1995

Re: CPI® Ventak® Prx® AICD™ System
Docket No. 94E-0315

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,407,288 filed by Cardiac Pacemakers, Inc. under 35 U.S.C. § 156. The patent claims the medical device product CPI® Ventak® Prx® AICD™ System, Premarket Approval Application (PMA) P910077.

In the November 15, 1994 issue of the Federal Register (59 Fed. Reg. 58,848), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before May 15, 1995, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Peter Forrest
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